

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

**In re: Pharmaceutical Industry Average Wholesale Price Litigation**

MDL No. 1456

### This Document Relates to:

Civil Action No. 01-12257-PBS

*U.S. ex rel. West v. Ortho-McNeil  
Pharmaceutical, Inc., et al.*, No. 03-8239  
(N.D. Ill.)

Hon. Patti B. Saris

**RELATOR’S MEMORANDUM IN OPPOSITION TO DEFENDANT’S MOTION TO  
DISMISS WEST’S CLAIM FOR “MARKETING THE SPREAD TO HOSPITALS”**

## A. INTRODUCTION

Relator's Second Amended Complaint (SAC) alleges that Ortho-McNeil marketed a spread of up to 108% for the 500 mg dose of Levaquin IV. Specifically, the SAC alleges that between 1997 and 2000, Ortho-McNeil's reported AWP for a 500 mg dose of Levaquin IV was \$39.60; that by virtue of rebates, purchasers' per dose actual acquisition costs were as low as \$19; and that the difference between Ortho-McNeil's reported AWP and the actual acquisition cost created a spread of up to 108%. This easily satisfies Rule 9(b) as applied by this Court to AWP-based fraud claims. Because the SAC satisfies Rule 9(b) and the AWP pleading standard set forth in earlier orders in this MDL, Ortho-McNeil's motion to dismiss for failure to plead the fraudulent AWP must be denied.

## B. PROCEDURAL HISTORY

On February 19, 2008, this Court issued its Memorandum and Order on Ortho-McNeil's first and second motions to dismiss, which sought dismissal of the Relator's First Amended

Complaint (“FAC”) for lack of subject matter jurisdiction, failure to state a claim under Rule 12(b)(6) and failure to plead the circumstances of Ortho-McNeil’s fraud with the particularity required by Rule 9(b). The Court held, *inter alia*, that it has subject matter jurisdiction over the claim that Ortho-McNeil marketed the spread between the reported Average Wholesale Price (“AWP”) of Levaquin and the Medicare reimbursement for Levaquin. Memorandum and Order dated February 19, 2008, Docket Entry 5056 (“Memorandum and Order”).

In addition to determining its own subject matter jurisdiction, this Court also held that the FAC did not allege the AWP fraud with the specificity required by Rule 9(b) and this Court’s AWP fraud pleading standard set forth in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 307 F.Supp.2d 196 (D.Mass. 2004). Memorandum and Order at p. 43. This Court directed Relator to amend the FAC “to state with specificity the allegedly fraudulent spread” or face dismissal under Rule 9(b). Memorandum and Order at p. 46.

Relator then filed his SAC alleging that between 1997 and 2000 the reported AWP for 500 mg doses of Levaquin IV was \$39.60; that by virtue of rebates Ortho-McNeil paid to purchasers, purchasers’ actual acquisition costs were as low as \$19 per 500 mg dose of Levaquin IV; and that the difference between the reported AWP and the actual acquisition costs created a spread of up to 108%. Ortho-McNeil then filed the instant motion, again seeking dismissal of the AWP claims. Ortho-McNeil’s motion is a classic straw man argument. It asserts – falsely – that the AWP claims in the SAC relate *solely* to sales to hospitals, and then claims that dismissal is required because AWP is irrelevant to hospital reimbursement. This argument fails because the first proposition, that the SAC is limited to hospitals, is manifestly false. The SAC makes allegations with respect to “physicians and other medical providers” (SAC ¶¶ 62 and 63), “hospitals and other institutional providers” (SAC ¶ 72), and “purchasers” (SAC ¶ 76). Because

the SAC applies to all purchasers, not merely hospitals, Ortho-McNeil's argument that Medicare does not reimburse *hospitals* based on AWP cannot lead to dismissal of the AWP claim.

**C. THE FACTS ALLEDGED IN THE SAC EASILY MEET THE FRAUDULENT AWP PLEADING STANDARD**

On this motion to dismiss, the Court must accept as true all well-pleaded facts alleged in the SAC, including all reasonable inferences therefrom. *Clark v. Boscher*, 514 F.3d 107,112 (1<sup>st</sup> Cir. 2008) (citation omitted). A complaint survives Rule 12(b)(6) when it contains well-pleaded facts with enough heft to "show that [plaintiff is] entitled to relief." *Id.*, quoting *Bell Atlantic Corp. v. Twombly*, --- U.S. ----, 127 S.Ct. 1955, 1959, 167 L.Ed.2d 929 (2007). Because this action arises under the False Claims Act, the SAC must also allege with particularity the circumstances constituting the fraud. Rule 9(b), Fed.R.Civ.P. Where, as here, the alleged false claims were submitted by third parties rather than Ortho-McNeil, "the relator need not allege the details of the particular claims, so long as 'the complaint as a whole is sufficiently particular to pass muster under the FCA.'" Memorandum and Order at p. 43; *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1<sup>st</sup> Cir. 2007).

In the context of pleading AWP fraud, this Court has previously found that in order to satisfy 9(b), an AWP-based claim must allege "(1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F.Supp. 2d 198, 208 (D.Mass. 2004), quoting *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F.Supp.2d 172, 194 (D.Mass. 2003). The SAC meets this standard. The SAC alleges that "[b]eginning in 1997, Ortho-McNeil embarked on an aggressive strategy of paying kickbacks and unlawful remuneration to **physicians and other medical providers** to capture a share of the fluoroquinolone market" and that "by late 2001, Levaquin held

approximately a 40% share” of that market. SAC at ¶ 62 (emphasis added). It alleges that “[f]rom 1997 to 2000, the Average Wholesale Price for 500 mg of Levaquin IV was \$39.60.” *Id.* at ¶ 76. It alleges that “Ortho-McNeil employed a multi-tiered rebates system, whereby **purchasers** (such as hospitals) would pay the highest rate for 500 mg of Levaquin IV, which was \$32, throughout the year.” *Id.* (emphasis added, parenthetical in original). The SAC further alleges that Ortho-McNeil paid rebates that resulted in “eight actual levels of pricing (\$32, \$31, \$29, \$27, \$25, \$23, \$21 and \$19), with lower prices being given to **purchasers** with larger market shares” *Id.* (emphasis added, parenthetical in original). The SAC further alleges that the spread “between what the **purchasers** paid for the 500 mg of Levaquin and the AWP exceeded 30% for all **purchasers** who paid from \$29 to \$19” and that “this ‘spread’ was 108% if the **purchaser** received the highest discounted rate of \$19 per dose.” *Id.* (emphasis added).

In short, the SAC meets the fraudulent AWP pleading standard as to all purchasers – not just hospitals. The issue of whether the government has been injured by the submission of claims by hospitals pertains solely to the amount of damages the government has sustained.

#### **F. Conclusion**

The SAC alleges Ortho-McNeil committed AWP-related fraud in connection with marketing and sales not just to hospitals, but also to physicians, medical providers, other institutional providers, and purchasers. The SAC alleges (1) the specific drug that was purchased from defendant – here Levaquin, (2) the allegedly fraudulent AWP for each drug - here, an AWP of \$39.60 and a spread of 108%, and (3) the name of the specific plaintiff that purchased the drug – here the United States of America. Ortho-McNeil’s motion must be denied.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

John A. Bruegger, an attorney, hereby certifies that on May 1, 2008, he electronically filed the foregoing with the Clerk of the United States District Court for the District of Massachusetts using the Court's CM/ECF system.

A copy of the foregoing also has been served on May 1, 2008 on the following individuals by depositing a copy in the U.S. mail, first-class postage pre-paid:

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